DOM requires prior authorization of certain covered drugs that have been approved by the Food and Drug Administration (FDA) for specific medical conditions. The approval criteria are recommended by DOM's Pharmacy and Therapeutics Committee and are based on information from the FDA, manufacturers, and medical literature. The prior authorization process is managed through the DOM Pharmacy Benefits Manager.

Prescription Drugs Requiring Prior Authorization

~~These prescription drugs were chosen based on the high potential for misuse and/or abuse~~. Prior authorization allows DOM to ensure that these prescription drugs are used ~~responsibly~~ appropriately and as they are intended. The following drugs/drug classes require prior authorization:

- ~~Enbrel~~
- Enteral Nutrition
- Immunosuppressants
- ~~Oral Sustained Release Opioid Agonists~~
- Synagis
- Xenical

Prior Authorization Process

Processes related to prior authorization for prescription drugs must be handled according to the procedures set forth by the Pharmacy Benefits Manager.

Refer to Section 1.11 Retrospective DUR Information for information related to the Pharmacy Benefits Manager.

Enteral Nutrition

Enteral nutrition is used as a nutritional replacement for patients who are unable to get enough nutrients in their diet. These formulas are taken by mouth or through a feeding tube and are used by the body for energy and to form substances needed for normal body functions.

DOM covers enteral nutrition when the following criteria are met:

1. For beneficiaries age 21 and over, the requested enteral nutritional must be the sole source of nutrition.

2. For beneficiaries under the age of 21, specialized feeding must constitute more than 50% of nutritional needs. A qualifying diagnosis is required.

3. The unique composition of the formula must contain nutrients the beneficiary is unable to obtain from food.

4. The composition of the formula must represent an integral part of treatment of the specified diagnosis and/or condition.

5. It must be documented that the beneficiary is unable to tolerate nutrients orally to sufficiently maintain life. The beneficiary is either unable to take oral nutrition or unable to tolerate oral intake.

6. Consideration is not given to accommodate psychological or behavioral conditions, food preferences, allergies, loss of appetite, or non-compliance with a specialized diet.

Documentation to support coverage of enteral nutrition must be maintained in the beneficiary's medical record. Documentation must include the following:

a. Specific diagnosis related to the beneficiary's inability to take or eat regular food

b. For oral feedings, list economic alternatives that have been tried. For beneficiaries age 21 and over, also list laboratory values for albumin or total protein.

c. Amount needed per day

d. Duration of treatment

e. Height, current weight, and recent weight loss

f. Specific prescription identifying levels of individual nutrient(s) that is required in increased or restricted amounts.

A prior authorization for enteral nutrition is for the nutritional product only and does not include supplies necessary to administer the nutrient.

Please note that Medicare must be billed first if the beneficiary is dually-eligible for Medicare and Medicaid.

Enteral nutritional replacements are not covered for residents in a long-term care facility, i.e. nursing home, ICF MR, etc. as these products are included in facilities' per diem rate.

Etanercept/Enbrel

DOM covers Etanercept/Enbrel when the following criteria are met on the **initial request**:

1. The beneficiary has a diagnosis of Rheumatoid Arthritis (RA).

2. The beneficiary has failed trials of at least one NSAID and one local/oral steroid without success.

3. The beneficiary has failed a trial of a least one prior DMARD and is currently on or has failed the second DMARD. Other DMARDs include:
    a. Gold
    b. Penicillamine
    c. Plaquenil (Hydroxychloroquine)
    d. Methotrexate (Rheumatrex)
    e. Sulfasalazine

DOM covers Etanercept/Enbrel for **renewal requests** with documentation of demonstrated effectiveness.

Immunosuppressants

DOM covers immunosuppressants when the following criteria are met:

1. The beneficiary must have a diagnosis of one of the following:
    a. Kidney, liver or heart allogenic transplant
    b. Rheumatoid arthritis
    c. Psoriasis
    d. Nephrotic Syndrome
    e. Stevens-Johnson Syndrome

2. Documentation must reflect that blood levels are monitored regularly.

The FDA recommends that the prescriber be experienced in managing post-transplant patients on immunosuppressant therapy.

Please note that Medicare must be billed first if the beneficiary is dually eligible for Medicare and Medicaid.

Oral Sustained Release Opioid Agonists

Patients appropriate for oral sustained release (SR) opioid agonists have chronic, severe pain that has not responded to alternative pain management choices, such as schedule II opioid agonists, physical therapy, cognitive behavioral techniques and/or medical techniques.

DOM covers oral SR opioid agents when the following criteria are met:

1. The beneficiary must have a diagnosis of one of the following:

    a. Cancer (ICD-9 codes 141.0-208)
    b. Arthropathies (ICD-9 codes 715.01-715.9)
    c. Spinal neurological disorders (ICD-9 codes 720-725)
    d. Other ICD-9 codes with supporting documentation

2. If the beneficiary does not have a diagnosis noted above, the prescriber must provide additional medical justification for the absence of alternative therapies in debilitated patients.

3. The beneficiary must have no contraindications such as:
    a. Hypersensitivity to opiates
    b. Respiratory depression/ hypoxia/hypercarbia
    c. Severe asthma or COPD
    d. Paralytic Ileus

The daily dosage intervals of oral sustained-release opioid agonists should not exceed manufacturer guidelines or FDA requirements.

For opioid dependent patients, the prescriber must provide documentation of a titration-weaning schedule.

Palvizumab (Synagis)

DOM covers Synagis when a beneficiary meets the criteria in one of the four following categories:

Category 1 — Prematurity of ≤ 28 weeks gestation
— Age: ≤ 1 year old

Category 2 — Prematurity of 29-32 weeks gestation
— Age: ≤ 6 months at the start of Respiratory Syncytial Virus (RSV) Season

Category 3 — Prematurity of ≤35 weeks gestation
— Age: 0-2 years old
— Diagnosis: Chronic Lung Disease (CLD) and ongoing medical treatment for CLD
— (supplemental oxygen, steroids, bronchodilators or diuretics) within the last 6 months

Category 4 — 33-35 weeks gestation
— Age: Birth- 6 months old during RSV season
— Risk factors as noted below are present and documented
— No diagnosis of CLD is required.

Extending beyond age two years may be considered on an individual basis when supported by clinical documentation of extreme necessity.

Prior authorization will end at age two (last day of child's birthday month).

Prior authorization is granted during RSV season only (usually October through March).

RSV Risk Factors:

One of the following is considered sufficient:

- Hemodynamically significant Congenital Heart Disease (simple, small Atrial Septal Defects (ASD), Ventricular Septal Defects (VSD), and Patent Ductus Arteriosus (PDA) are not eligible).
- Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)
- Chronic lung disease requiring medical treatment within the past 6 months (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodialators or ventilation-dependent,

Or

Must have two of the following:

- Exposure to tobacco smoke in the home
- School age siblings
- Multiple birth
- Day care
- Severe neuromuscular disease
- Congenital airway abnormalities

Xenical

DOM covers Xenical when the following criteria are met:

1. A beneficiary must be at least 21 years of age.

2. For the initial request, a beneficiary must have all of the following criteria:
    a. A diagnosis of diabetes, hypertension, or hyperlipidemia
    b. A Body Mass Index (BMI) of 35 or greater
    c. Documentation in medical record of prior physician supervised exercise/diet regimen
    d. Has planned adjunctive therapy
    e. Has been educated and understands risks/adverse reaction/complications
    f. Have no contraindications such as Chronic Malabsorption Syndrome, Hypothyroidism, Cholestasis, or Hypersensitivity to Xenical or to any of its components.

3. For 1st renewal request, the beneficiary must have documentation of 7% body weight or greater within 3 months.

4. For subsequent renewals, the beneficiary must have documentation of no weight gain.